IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

UNITED STATES OF AMERICA
ex. rel. JOHN DOE

Plaintiff-Relator,

v.

CASE NO. 3:20-cv-00803-CMC

WILLIAM THOMAS ODOM, II, M.D.

DISPOSITIVE MOTION

Defendant.
_____/

DEFENDANT'S MOTION TO DISMISS PLAINTIFF-RELATOR'S COMPLAINT

Defendant WILLIAM THOMAS ODOM, II, M.D., through undersigned counsel and pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), hereby files this motion to dismiss Plaintiff-Relators Complaint (Doc. 1), and in support thereof state as follows:

I. BACKGROUND

A. PARTIES

Defendant William Thomas Odom, II, M.D. is a medical doctor who is board certified in anesthesiology and has practiced medicine since 1992. Compl. at ¶¶ 10, 11.

Relator John Doe ("Relator") is allegedly a medical doctor Board Certified by the American Board of Surgery in General Surgery-Hand Surgery. Id. at ¶ 7. Relator's medical practice location is unknown.

B. ALLEGATIONS

Relator alleges in his complaint that Defendant violated the False Claims Act ("FCA"), pursuant to 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B) by knowingly presenting or causing to be presented false or fraudulent claims for payment or approval to Government

Healthcare Programs. Compl. at ¶¶ 61-64. Specifically, Relator alleges Defendant falsely and fraudulently billed these programs under CPT codes 64450, 95909, and 76492.

C. PROCEDURAL HISTORY

Relator filed his initial complaint under seal on February 21, 2020. (Doc. 1). On May 22, 2020, the United States declined to intervene on Relator's behalf. (Doc. 10). The matter was released from under seal by court order on May 27, 2020. (Doc. 11). Summons was issued as to Defendant on May 27, 2020. (Doc. 13).

II. STANDARD OF REVIEW

When considering a motion to dismiss brought under Rule 12(b)(6), the court accepts as true all the allegations in the complaint and construes them in the light most favorable to the plaintiff. Jackson v. Bellsouth Telecomms., 372 F.3d 1250, 1262 (11th Cir. 2004). However, the Supreme Court explains that:

> "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level."

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal citations omitted). In addition, courts are not "bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986). Facts that are "merely consistent with" liability do not establish a plausible claim to relief. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Furthermore, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id.

To survive a motion to dismiss, Relator must satisfy both Fed. R. Civ. P. Rule 8 and Rule 9(b) pleading requirements. Under Rule 8, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to `state a claim to relief that is plausible on its face.'" Ashcroft, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 570). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Twombly at 556.

Rule 9(b)'s particularity requirement supplements Rule 8(a)'s demand that a claim is "plausible on its face." Ashcroft, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 570). Rule 8(a) prohibits any claims that are merely conceivable rather than plausible. Iqbal, 556 U.S. at 680 (quoting Twombly, 550 U.S. at 570). A claim is merely conceivable and not plausible if the facts pleaded are consistent with both the claimed misconduct and a legal and *"obvious alternative explanation."* Id. at 682 (quoting Twombly, 550 U.S. at 567) (emphasis added). A plaintiff's failure to plead fraud with particularity under Rule 9(b)'s pleading requirements "is treated as a failure to state a claim under Rule 12(b)(6)." Harrison v. Westinghouse Savanna River Co., 176 F.3d 776, 783 n.5 (4th Cir. 1999).

Claims arising under 31 U.S.C. §§ 3729(a)(1)(A) and (B) of the FCA are fraud-based claims that must satisfy Rule 9(b) 's pleading standard. United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 455–56 (4th Cir. 2013) (citing States ex rel. Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1311 (11th Cir. 2002) (holding that Rule 9(b) 's particularity requirement "does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting

illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.")). “Rule 9(b)’s particularity requirement serves as a necessary counterbalance to the gravity and "quasi-criminal nature" of FCA liability. United States ex rel. Grant v. United Airlines Inc., 912 F.3d 190, 197 (4th Cir. 2018) (quoting United States ex rel. Atkins v. McInteer , 470 F.3d 1350, 1360 (11th Cir. 2006).

The Fourth Circuit has "adhered firmly to the strictures of Rule 9(b) in applying its terms to cases brought under the Act." Nathan, 707 F.3d at 456 (citing Wilson, 525 F.3d at 379-80 (explaining the requirements of Rule 9(b) and affirming dismissal for failing to comply); Harrison, 176 F.3d at 789-90 (same). “The multiple purposes of Rule 9(b), namely, of providing notice to a defendant of its alleged misconduct, of preventing frivolous suits, of 'eliminat[ing] fraud actions in which all the facts are learned after discovery,' and of 'protect[ing] defendants from harm to their goodwill and reputation,' are as applicable in cases brought under the Act as they are in other fraud cases.” Id. (internal citation omitted) (quoting Harrison, 176 F.3d at 784).

There are two ways to adequately plead presentment under Rule 9(b). First, a plaintiff can "allege with particularity that specific false claims actually were presented to the government for payment." Id. at 457. This standard requires the plaintiff to, "at a minimum, describe ‘the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.’" United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 379 (4th Cir. 2008) (quoting Harrison, 176 F.3d at 784). Alternatively, a plaintiff can allege a pattern of conduct that would "necessarily have led[ ] to submission of false claims" to the government for payment. Nathan at 457.

The critical question is whether the defendant caused a false claim to be presented to the government, because liability under the Act attaches only to a claim actually presented to the

government for payment, not to the underlying fraudulent scheme. Id. (citing United States v. Rivera, 55 F.3d 703, 709 (1st Cir.1995)). Therefore, when a relator fails to plead plausible allegations of presentment, the relator has not alleged all the elements of a claim under the Act. See Clausen,290 F.3d at 1313 ("[W]e cannot be left wondering whether a plaintiff has offered mere conjecture or a specifically pleaded allegation on an essential element of the lawsuit.").

Relator's allegations fail to fulfill the requirements of Rule 8(a) and Rule 9(b), because they are based only on his personal opinion, which Relator believes could have led to false submissions for "many or most of the claims…" Compl. at ¶¶ 41, 51, 60. Relator alleges with no particularity any specific false claims that were actually presented to the government, but only provides generalized CMS claim submission statistics which are easily explained by Defendant's participation in the government recognized American Association of Sensory Electrodiagnostic Medicine ("AASEM") clinical trial study, and are at best Relator's own speculation couched as factual allegations which are "merely consistent with liability" Ashcroft at 678. "When a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." Nathan at 458. Relator's complaint fails to plead the elements on an FCA claim with sufficient particularity to satisfy Rule 9(b) and should therefore be dismissed in its entirety.

III. DISCUSSION

A. Introduction

Relator is part of a new breed of whistleblower. Unlike traditional whistleblowers, who gain personal knowledge of false claims through employment or personal involvement in a Defendant's business or practice, new whistleblowers act similar to sleuths whose vantage point

is that of an outsider looking in.[1] As Relator has done here, these whistleblowers claim knowledge in a particular specialty to stitch together pieces of publicly available data to allege elements of potential wrongdoing in an attempt to gain a monetary benefit.

Relator anonymously alleges he is a medical doctor Board Certified in General Surgery-Hand Surgery. Compl. at ¶ 7. He does not claim to be a doctor in South Carolina, and seems to remain anonymous for no reason, since he is not an employee and has never been an employee of Defendant who could face retaliation if his identity was exposed. While he claims to use anesthetic blocks and injections in daily surgery, he does not allege to be certified in anesthesiology or allege to have any knowledge or experience conducting the specific medical procedures routinely performed by Defendant. Defendant is board certified in anesthesiology, yet Relator intentionally mischaracterizes Defendant as only a "pain management physician" in what Defendant can only assume is Relator's attempt to disqualify him from administering treatment under CPT 64450, 76942, and 95909. Compl. at ¶ 59.

Importantly, Defendant enrolled as a Principal Investigator in the AASEM sponsored Physician's Clinical Trial Policy NCT No. 01979367 in years 2016 and 2017.[2] The objective of this study is to demonstrate the non-inferiority of devices in question (Axon II 250 Hz small pain fiber (spf) testing device, Anodyne/MIRE, TENS, NBPM (Nerve Block pain management) for lower extremity neurological ischemia. Id. All of this information is publically available online at clinicaltrials.gov. This study provides an obvious alternative explanation for Defendant's high

[1] See Mary Inman, Esq. and Max Voldman, Esq., *Integra Med Analytics Loses Battle to Establish New Breed of Corporate Whistleblower Outsiders*, RACmonitor, June 3, 2020, https://www.racmonitor.com/integra-med-analytics-loses-battle-to-establish-new-breed-of-corporate-whistleblower-outsiders

[2] See https://clinicaltrials.gov/ct2/history/NCT01979367?V_26=View#StudyPageTop ; A summary of the study results are available at aasem.org, https://cdn.shopify.com/s/files/1/0915/1318/files/odom_17_sum.pdf

volume of Medicare claims under CPT code 64450, 95909, as services performed by Defendant under this study were submitted to Medicare in years 2016 and 2017. This study was found to be properly registered and valid in a final agency decision rendered by Administrative Law Judge ("ALJ") Marilyn Faulkner.[3]

Further, Relator's action should be rendered moot, as Defendant and Defendant's medical practice are already experiencing collection activity for the same services referenced in Relator's complaint.[4] 31 U.S.C. § 3730(e)(4)(i). With appeals pending, Relator attempts to duplicate the government's current collection efforts and should not be able to seek an unlawful windfall. 31 U.S.C. § 3730(b).

The FCA also contains a "public disclosure bar," which is triggered when the fraud allegations were in the public domain before a *qui tam* relator filed suit. 31 U.S.C. § 3730(e)(4). Relator's complaint should be dismissed pursuant to the public disclosure bar, because the government was previously aware of substantially the same allegations underlying Relator's claims. Id. Defendant's practice has been reviewed by the Centers for Medicare and Medicaid services ("CMS") for the years relative to Relator's complaint. This is evidenced by the governments' action to recoup Defendant's previous reimbursement for Defendant's Medicare claims under CPT code 64555 pursuant to the same LCDs referenced in Relator's complaint. Services performed during the same study using the Axon-II were billed by Defendant under CPT code 95909, which the government may choose to pursue for recoupment if desired.[5]

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[3] See ALJ No. 1-3398458604. See also National Coverage Determination 310.1.
[4] See Treasury Ref. No. 10339998 and Letter No. 1-7457357490.
[5] CMS has already sought recoupment for services performed using the Axon-II in other administrative cases, which resulted in favorable decisions. Such decisions include: (1) ALJ Appeal No.: 1-3339845860; (2) ALJ Appeal No.: 1-67387421; (3) ALJ Appeal No.: 1-322110643; (4) QIC Medicare Appeal No.: 1-4157913764; (5) QIC Medicare Appeal No.: 1-

Compl. at ¶ 43-45, 59. The government is also already aware of Defendant's claims under CPT 76492 as discussed *infra*. Relator's complaint provides the government with no additional notice of potential wrongdoing by Defendant.

Relator fails to satisfy the "original source" exception to overcome the public disclosure bar. 31 U.S.C. § 3730(e)(4)(B). Relator spends a majority of his complaint citing CMS data, LCD code content, and inapplicable American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) guidance. Relator's alleged "investigation" and "experience" provides no independent knowledge which could materially add to the publicly disclosed allegations or transactions present online and in several administrative cases. Compl. at ¶¶ 11, 38, 39, 53.

Finally, Relator fails to satisfy the particularity requirements of Rule 9(b). Relator only manages to allege that he "believes many or most of the claims Defendant submitted" were false, but fails to identify a single false claim submitted to the government or payment. He instead uses AANEM guidance, generalized CMS statistics, and his own "experience" (which does not align with Defendant's experience or qualifications) to claim Defendant's services were not medically necessary and are therefore consistent with false claims. Relator fails to even establish a pattern of conduct which would necessarily have led to a false claim being submitted. He instead asks the court to assume Relator's statistical recitations could only be explained by fraud. Relator's complaint is devoid of any allegations sufficient to survive a motion to dismiss.

5304682396; (6) QIC Medicare Appeal No.: 1-5304682468. Another decision is currently on appeal regarding LCD 35048. See Decision No. CR5587, Decision Date: April 15, 2020.

B. Relator's complaint should be rendered moot due to pending government recoupment.

Relator's action should be rendered moot, as Defendant is currently facing recoupment for Medicare claims submitted under CTP code 64450.[6] Defendant submitted claims under these codes for services performed within the AASEM sponsored Physician's Clinical Trial Policy properly registered through the National Library of Medicine ("NLM") and posted publicly at clinicaltrials.gov under the national clinical trial number 01979367. This study began in March 2012 and has an estimated study completion date of January 2023. Defendant enrolled in this study for years 2016 and 2017. The objective is to demonstrate the non-inferiority of devices in question (Axon II 250 Hz small pain fiber (spf) testing device, Anodyne/MIRE, TENS, NBPM (Nerve Block pain management) for lower extremity neurological ischemia. Services performed during the study using the Axon-II were billed by Defendant under CPT code 95909. Defendant utilized nerve block injections for patients' pain management in his study and billed Medicare under CPT code 64450.

Relator's allegations expose his deficient research prior to bringing this action, as the details of Defendant's clinical trial are easily accessible at clinicaltrials.gov. Compl. at ¶¶ 37-41. Further, to learn more about the study, the website invites any member of the public to contact the research staff using the contact information readily available on the website. Even minimal research would have revealed Defendant's significant involvement in NCT No. 01979367, and explain Defendant's volume of claims under CPT code 64450 and 95909. Relator instead bases his allegations of fraud on the "customary practices and standards of care in South Carolina", and Defendant's "reputation in the professional community", demonstrating his lack of personal and

[6] See Treasury Ref. No. 10339998 and Letter No. 1-7457357490.

professional knowledge regarding Defendant's practice, and a misunderstanding of the targeted patient population involved in Defendant's study and general practice. Compl. at ¶¶ 37-39.

Further, the administrative decisions leading to the recoupment of reimbursement for services claimed by Defendant utilized LCD 37642 to disallow the use of nerve blocks for lower extremity pain due to ischemic circulatory disorders. Relator's allegations mirror these decisions, and use the same LCD to support his allegations. Compl. at ¶¶ 32-34. Relator allegations are moot, as Relator brings forth no new information which could aid the government in recouping additional money from Defendant for services rendered under CPT code 64450.

Relator's allegations regarding CPT code 76492 should also be rendered moot, because allegations regarding CPT 64450 are moot. CPT 76942 is a guidance code and would not be billed independently. Compl. at ¶ 59. Section V of Relator's complaint in its entirety rests on his allegation that because "Defendant's CPT 64450 injections are not medically necessary…", Defendant's claims under CPT 76942 are also false. Compl. at ¶ 60. Therefore Relator's allegations regarding both CPT 76942 and 64450 should be rendered moot.

Further, Relator's allegations regarding CPT 95909 should be rendered moot. The government has already initiated several administrative actions to recoup money from physicians utilizing the Axon-II.[7] Relator inconstant claims fail to put the government on any additional notice, and instead inaccurately claims Defendant is conducting EMGs (discussed *infra*).

C. Relator's claims are barred by the FCA's public disclosure bar.

Even if this court does not render Relator's action moot, Relator's claims are still barred by the FCA public disclosure bar and must be dismissed. The FCA public disclosure bar

[7] Such decisions include: (1) ALJ Appeal No.: 1-3339845860; (2) ALJ Appeal No.: 1-67387421; (3) ALJ Appeal No.: 1-322110643; (4) QIC Medicare Appeal No.: 1-4157913764; (5) QIC Medicare Appeal No.: 1-5304682396; (6) QIC Medicare Appeal No.: 1-5304682468.

prohibits relators from bringing a suit based on allegations that have already been disclosed to the public, unless the relator qualifies as an original source. See 31 U.S.C. § 3730(e)(4). Specifically, the FCA provides that:

> The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

Id. at § 3730(e)(4)(A). The FCA then defines "original source":

> For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

Id. at § 3730(e)(4)(B).

The public-disclosure bar aims "to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits" in which a relator, instead of plowing new ground, attempts to free-ride by merely reiterating previously disclosed fraudulent acts. Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 295 (2010). "As amended…the public-disclosure bar no longer requires actual knowledge of the public

disclosure, but instead applies if substantially the same allegations or transactions were publicly disclosed." United States ex rel. May v. Purdue Pharma L.P., 737 F.3d 908, 917 (4th Cir. 2013).

A district court resolving a public disclosure bar challenge must, on a claim by claim basis, apply a three-prong analysis to determine whether the public disclosure bar applies: (i) whether there was a public disclosure, (ii) whether the relators' allegations are substantially the same allegations or transaction, and (iii) whether the relators are entitled to original source status. See United States ex rel. Wilson v. Graham County Soil & Water Conservation Dist., 528 F.3d 292, 299 (4th Cir.2008), rev'd on other grounds by Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280 (2010).

A district court deciding whether there has been a qualifying "public disclosure" must determine (i) whether the disclosure occurred via a source specifically identified in the statute, (ii) whether the disclosure was made "public" prior to the filing of the relevant complaint, and (iii) whether the public disclosure revealed "allegations or transactions." See 31 U.S.C. § 3730(e)(4)(A).

Although the Fourth Circuit has not construed the meaning of the phrase "publicly disclosed," this Court adopts the construction of other circuits addressing the issue. Those circuits generally agree that "publicly disclosed" means that a disclosure has been made to the general public, placed in the public domain, or made in a manner such that it is equally available to a stranger to the fraud should the stranger choose to look for the information. United States ex rel. Saunders v. Unisys Corp., Case No. 1:12-cv-00379 (GBL/TCB), 10 (E.D. Va. Mar. 21, 2014); See United States ex rel. Beauchamp v. Academi Training Ctr., 933 F. Supp. 2d 825, 840 & n.28 (E.D. Va. 2013).The Fourth Circuit also has not specifically elucidated the phrase "allegations or transactions," but the many courts that have done so have adopted the D.C.

Circuit's interpretation of the phrase. See Davis, 753 F.Supp.2d at 580 n. 17 (collecting cases). In essence, under the D.C. Circuit's test, a qualifying "public disclosure" must either reveal: (i) an allegation of fraud or (ii) the true state of facts and a false state of facts, from which a fraud may be inferred. See Springfield, 14 F.3d at 654-55. As the Sixth Circuit has explained, either type of disclosure satisfies the purpose of the public disclosure requirement, namely to "put the government on notice to the possibility of fraud." United States ex rel. Gilligan v. Medtronic, 403 F.3d 386, 389 (6th Cir.2005).

The new definition of an "original source" still imposes a barrier to putative relators after public disclosure has occurred, and the amendment only opens the door to late-comer relators who possess knowledge that can materially add to what has already been publicly disclosed. Relator fails to qualify as an original source under the statute, as he pleads no new material information which is outside the existing public domain.

i. Relator's allegations and transactions contain substantially the same allegations publically disclosed prior to filing his complaint.

Relator's complaint contains substantially the same allegations and transactions which were publicly disclosed prior to filing the subject complaint. Courts within the Fourth Circuit have held that "[a] public disclosure and the instant claims are substantially the same if the earlier disclosure puts the Government on notice of wrongdoing such that the Government could have started an investigation." United States ex rel, Vitale v. MiMedx Grp., Inc., 381 F. Supp. 3d. 647, 657 (D.S.C. 2019); see Fadlalla v. DynCorp Int'l LLC, 402 F. Supp. 3d 162, 181-85 (D. Md. 2019). The government has not only started an investigation regarding these Relator's same allegedly false Medicare claims, but has already conducted administrative hearings and rendered

decisions against Defendant and other physicians who use the Axon-II.[8] In effect, Relator is targeting a Defendant who has already been the subject of several identical administrative actions.

The clinical study involving the transactions billed under CPT code 64450 and 95909 were publicly disclosed online prior to Relator filing the subject complaint.[9] In Defendant's 2016 clinical trial results, which are available online at assem.org, Defendant explains the methods used for enrolled patients' pain management, stating: "To sustain the patient through the rather painful nerve reawakening process, and to allow for progressive ramping up of intensity of therapy at each subsequent visit, we provided NBPM via 8-10 cc's of lidocaine/bupivacaine (w/o epi) after each session."[10] These anesthetic injections explain the high volume of claims per enrolled patient under CPT Code 64450 in 2016 and 2017, and invalidate Relator's allegations that there "was no 'cluster' of symptoms or diagnoses that would indicate Defendant Odom's volume of repeat procedures are medically reasonable or necessary." Compl. at ¶ 38.

The allegations pertaining to CPT code 64450 were also publically disclosed through administrative hearings and decisions.[11] Defendant has already been required to pay back reimbursement for services rendered under this code, and continues to face additional

[8] Such decisions include: (1) ALJ Appeal No.: 1-3339845860; (2) ALJ Appeal No.: 1-67387421; (3) ALJ Appeal No.: 1-322110643; (4) QIC Medicare Appeal No.: 1-4157913764; (5) QIC Medicare Appeal No.: 1-5304682396; (6) QIC Medicare Appeal No.: 1-5304682468

[9] Courts have unanimously construed the term "public disclosure" to include websites and online articles. See Schindler Elevator Corp. v. U.S. ex rel. Kirk, 563 U.S. 401, 408 (2011) ("The other sources of public disclosure in § 3730(e)(4)(A), especially 'news media,' suggest that the public disclosure bar provides 'a broa[d] sweep.' "); Osheroff, 776 F.3d 805, 813 (11th Cir. 2015) (concluding that newspapers and publicly available websites qualified as "news media" under the public disclosure provision).

[10] William T. Odom, II, M.D., *2017 Summary Clinical Trial Results NCT # 01979367*, https://cdn.shopify.com/s/files/1/0915/1318/files/odom_17_sum.pdf?16450283569176905393

[11] Letter No. 1-7457357490. The invalidity of LCD 35048 is explained in further detail in Decision No. CR5587, Decision Date: April 15, 2020.

recoupment for these services. Relator attempts to summarize the related CMS data in an effort to materially add new information. However, Relator alleges no new information, but instead only regurgitates CMS data and LCD content already published and publically available in the administrative decisions rendered and Defendant's online study results.

Relator's allegations regarding CPT Code 95909 were also publically disclosed prior to filing the complaint. The details of defendant's clinical trial, as well as the 2016 clinical trial results, explain that Defendant utilized the Axon-II to conduct small pain fiber NCSs to objectively confirm impairment of enrolled patients' lower extremities to allow admittance into the study, with follow up NCSs conducted to document objective response of the nerve fibers.[12] These repeated NCSs were billed under CPT code 95909 for the nerve sites tested in the study. These patients did not just "arrive in Defendant's office" but were preselected to participate in Defendant's study. Compl. at ¶ 55. The publicly available study methodology and results explain why the study billed for the same amount of NCSs for each enrolled patient, who was required to return for 8 sessions. Therefore, contrary to Relator's allegations, it is both plausible and within the standard of care to have patients return "again and again". Compl. at ¶ 55.

Further, Relator's allegations regarding CPT 76492 are also barred by public disclosure. Ultrasound guidance, always billed in conjunction with a primary code like CPT 64450, is commonly used by anesthesiologists to guide them to the injection site for nerve block injections.[13] Compl. at ¶ 59. Relator alleges that because he believes CPT 64450 injections administered during 2016 and 2017 was medically unnecessary, ultrasound guidance performed under CPT 76492 for years 2014 through 2017 were also medically unnecessary. This makes

[12] See aasem.org
[13] Terkawi, A. S., Karakitsos, et al. *Ultrasound for the anesthesiologists: present and future*, TheScientificWorldJournal, Nov. 20, 2013, https://doi.org/10.1155/2013/683685.

little temporal sense. Relator confuses the services performed in furtherance of Defendant's clinical study, with ultrasound guidance performed in conjunction with nerve blocks performed outside of the study in Defendant's general practice.[14] Relator simply repeats publicly available CMS statistical data and drafts a CMS chart outlining the types of providers and how many times each type billed under Code 76942. All of this information statutorily qualifies as a public disclosure under the public disclosure bar.

The close similarities between Defendant's related administrative decisions and online trial study, and the allegations contained in Relator's later filed complaint constitute convincing evidence that the allegations in his *qui tam action* are barred by the FCA public disclosure bar. Relator's complaint should therefore be dismissed.

ii. Relator does not qualify for original source status

Under the FCA, a relator is barred from bringing a subsequent qui tam lawsuit asserting identical or similar allegations that had been publicly disclosed unless he meets the "original source" exception. Under the FCA, as amended in 2010, a relator qualifies as an "original source" if he "has knowledge that is independent of and materially adds to the publicly disclosed allegations . . . and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B).

Relator chooses to remain anonymous in this action. He alleges to be board certified in hand surgery, but does not allege to be board certified in anesthesiology. He does allege to practice in South Carolina, know Defendant personally or professionally, or have any personal knowledge regarding Defendant's practice. Relator only claims experience in performing nerve

[14] As evident in Defendant's trial methods, he did not use ultrasonic guidance during his study. See https://cdn.shopify.com/s/files/1/0915/1318/files/odom_17_sum.pdf?16450283569176905393.

blocks in the hand, which he believes qualifies him to formulate medical opinions regarding the medical necessity of all of Defendant's procedures.

While Defendant recognizes that Relator may use public disclosures to support his allegations, Relator must still possess knowledge that can materially add to what has already been publicly disclosed and puts the government on notice of further potential wrongdoing. Relator's complaint almost entirely consists of CMS data, LCD references, and inapplicable AANEM guidance from inapplicable LCDs. Relator attempts to gain "original source" status by summarizing CMS data to create general graphs and tables, and use basic mathematics to calculate the amount of time it would take Defendant to perform 624 EMGs in 1 year. These calculations created from public disclosures fail to provide to any new information or independent knowledge outside the public domain and therefore fail to qualify Relator as an "original source".

Relator's claims regarding CPT 64450 are allegedly based on his personal "investigation and experience". Relator asserts this investigation revealed the related procedures were not medically necessary and therefore false, however, his "investigation" is based on the publically available "customary practices and standards of care in South Carolina" and a generic statement of Defendant's "reputation in the professional community". Compl. at ¶¶ 37-41. These repeated injections were part of Defendant's publically disclosed trial study as discussed *supra*. Relator's reasoning as to why Defendant's claims were allegedly false adds no other information other than CMS data from 2016 and 2017, which is readily disclosed online to the public.

Relator's allegations regarding CPT 95909 also lack any independent and material knowledge. Relator references LCD 35048 and AANEM guidance to support his allegations that Defendant's NCSs were not medically necessary and only conducted to "increase Defendant's

profits". Compl. at ¶ 55. Relator then proceeds to summarize the CMS data in a table and make an elementary mathematical calculation about the amount of time it would take Defendant to conduct 624 EMGs. These allegations demonstrate Relator's complete lack of education and experience in non-invasive small pain fiber NCSs.

While Defendant understands that the merits of a case are not argued in a motion to dismiss, Defendant finds it important to note that Relator's reference to LCD 35048 demonstrates a gross misunderstanding of the difference between the AANEM and AASEM and the different types of NCSs. The AANEM physician members use needle and shock tests on large non-pain signaling nerves.[15] The AASEM physician members perform painless non-intrusive tests on small nerves that signal pain.[16] Defendant's AASEM approved study utilizes the Axon-II to perform a non-invasive NCS to detect small pain fiber nerve function. These studies can be performed as many times as necessary and, unlike an EMG, uses no needles or invasive procedures. Relator is correct that neurologists routinely perform EMG's, but physicians like Defendant routinely conduct non-invasive tests on patients with small pain fiber disorders using devices like the Axon-II instead. Compl. at ¶¶ 48, 49.

Relator's misleading and unfounded allegations are all public disclosures which are the subject of several other previous administrative decisions. The government has already been put on notice of Defendant's utilization of the Axon-II to conduct NCSs, and may choose to recoup reimbursement based on LCD 35048 billed under CPT 95909. Therefore, Relator's allegations do not materially add any new information which could qualify him as an original source.

Further, Relator's allegations regarding CPT 76492 are misguided and contribute no independent knowledge to the information already publically disclosed. Relator conclusively

[15] For more information see aanem.org.
[16] For more information see aasem.org.

alleges that because he believes Defendant's anesthetic blocks billed under Code 64450 are not medically necessary, he believes the ultrasonic guidance used during these injections is also not medically necessary. Relator also conclusively alleges that Defendant "would generally not be referred patients with problems deep within the body" but does not claim to have knowledge of Defendant's patient demographic or any personal knowledge of Defendant's practice. Relator ignores the fact that Defendant is a board certified anesthesiologist, and contradicts himself by stating that ultrasonic guidance is typically claimed by anesthesiologists and providing a table showing that ultrasonic guidance is most commonly billed by anesthesiologists like Defendant. Compl. at ¶ 59.

Relator demonstrates that he possesses no personal or independent knowledge, lacks the medical education necessary to formulate medical opinions regarding his allegations, and instead bases his entire argument regarding CPT 76492 on the alleged medically unnecessary CPT 64450. Compl. at ¶ 59. Relator does not qualify as an independent source; therefore Relator's complaint should be dismissed in its entirety.

D. Relator fails to fulfill particularity requirement

Even if this court determines Relator's claims not barred under the FCA public disclosure bar, Relator still fails to plead his allegations with sufficient particularity to satisfy Rule 9(b).

Relator pleads his allegations as an outsider peeping in. He is incapable of alleging "at a minimum…'the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby" because he does not have any knowledge (neither personal nor obtained through other individuals) of Defendant's medical practice or patient demographic. United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 379 (4th Cir. 2008) (quoting Harrison, 176 F.3d at 784). Relator instead attempts

to allege a pattern of conduct that would "necessarily have led[ ] to submission of false claims" to the government for payment by citing CMS data and generalized allegations about procedures performed on patients in Defendant's practice. Nathan, 707 F.3d at 457.

While Defendant recognizes that Relator is not automatically disqualified from bringing a FCA claim by using publicly available statistics to allege a pattern of false claim submissions by Defendant, Relator has still failed to submit a claim which is plausible and not merely conceivable. A claim is merely conceivable and not plausible if the facts pleaded are consistent with both the claimed misconduct and a legal and "obvious alternative explanation." Iqbal, 556 U.S. at 680 (quoting Twombly, 550 U.S. at 567) (emphasis added). Relator provides no factual basis, aside from basic statistical summarization, for the court to conclude that "many or most of Defendant's claims submitted" plausibly constituted fraud.

Relator's allegations regarding CPT 64450 fail the requirements of Rule 9(b). Relator cites to CMS data to show Defendant allegedly claimed the code "more often than any other doctor submitting claims under Medicare Part B." Compl. at ¶ 35. Defendant's "volume of repeat procedures" is explained by his participation in the clinical trial study and general practice of anesthesiology. Instead of supporting these allegations with facts or information pertaining to Defendant's practice, Relator instead provides conclusory reasons he thinks Defendant's claims are false. This simply will not suffice. See Bell Atl. Corp. v. Twombly, at 555.

Relator instead cites inapplicable and invalid LCDs to support his allegations. For example, LCD 37642 has an effective date of October 1, 2015. National Coverage Determination ("NCD") 310.1 states routine costs in qualifying clinical trials, "as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials" are deemed to be covered. The NCD states further that "Medicare will cover

the routine costs of qualifying trials that either have been deemed to be automatically qualified or have certified that they meet the qualifying criteria unless HCFA's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries." As stated, the clinical trial has been upheld as valid through final agency decision. Relator's contrary allegations stating that these services are not covered by Medicare are completely baseless.

Further, since LCD 37642 has an effective date after the inception of Defendant's trial study, it does not apply to services conducted by Defendant in furtherance of this study. Even if the LCDs present in Relators complaint were relevant, Relator's formulaic recitation of these LCDs does not substitute the need for specific facts regarding the submission certain false claims themselves. Relator insists that because he believes Defendant's services are performed at a higher than national average and are allegedly "unnecessary and potentially risky" the services are somehow false. These conclusory allegations should not survive a motion to dismiss.

Relator does not provide any specific allegations regarding the submission of claims under CPT 76492, but instead claims that because Defendant's CPT 64450 injections were medically unnecessary, Defendant's services under CPT 76492 were also medically unnecessary. Relator's allegations regarding CPT 76492 therefore also fail the particularity requirements.

Relator further makes contradictory claims that because Defendant allegedly "would generally not be referred patients with problems deep within the body" and CPT 76492 is typically claimed by anesthesiologists, Defendant's claims must be false. Compl. at ¶¶ 58, 59. Relator fails to establish any pattern of conduct which would lead to a false submission of claims by Defendant, as Defendant is a board-certified anesthesiologist. By pleading such general

allegations, Relator requests that the court allow him to initiate a costly discovery process based on his own unqualified sneaky suspicion of Defendant's claims.

Relator's allegations regarding CPT 95909 also fail the requirements of Rule 9(b). These allegations are entirely based on Relator's incorrect assumption that Defendant is performing invasive EMGs on patients. As explained in the details of Defendant's trial study, he routinely uses the Axon-II, a non-invasive machine which documents the qualitative dysfunction of non-invasive small pain fiber nerves. All remaining allegations regarding CPT 95909 fail to reach a level of plausibility, because they are explained using the publically available information at aasem.org and cms.gov regarding Defendant's trial study.

Relator does not provide any specific allegations of false claim submissions, but instead substitutes these required specific allegations with his own self-proclaimed "experience and professional opinion." Compl. at ¶¶ 51, 55. Statistical data cannot meet these pleading requirements if, among other possible issues, it is also consistent with a legal and obvious alternative explanation.

Relator never alleges to have performed a small pain fiber NCS, or conducted nerve blocks for lower ischemia, but still formulates a medical opinion on the medical necessity of Defendant's claims and declares them fraudulent. This is a far cry from Rule 9(b)'s knowledge and particularity requirements. Relators complaint should therefore be dismissed in its entirety for failure to meet the requirements of Rule 12(b)(6) and Rule 9(b).

E. Discovery Will Not Cure Pleading Defects

Relator admits outright that "much of the documentary evidence necessary to prove the allegations is in the possession of Defendant and the United States". Compl. at ¶ 8. The "clear intent of Rule 9(b) is to eliminate fraud actions in which all the facts are learned through

discovery after the complaint is filed." Harrison at 789 (quoting United States ex rel. Stinson, Lyons, Gerlin Bustamante, P.A. v. Blue Cross Blue Shield of Georgia, Inc., 755 F. Supp. 1040, 1052 (S.D. Ga. 1990). Relator appears to be on a fishing expedition trying to hook anything which could support his allegations and lines his pockets.

As stated by the district court in Clausen "The particularity requirement of Rule 9 is a nullity if Plaintiff gets a ticket to the discovery process without identifying a single claim." United States ex rel. Clausen v. Laboratory Corp. of America, Inc., 198 F.R.D. 560, 564 (N.D. Ga. 2000). The court further explains:

> "If given such a ticket, the next stage of [the] litigation is clear. The Plaintiff will request production of every ... claim submitted by the Defendant [during the time period corresponding to Plaintiff's claims]. At that point, the Defendant may decide to settle the case to avoid the enormous cost of such discovery and the possible disruption of its ongoing business. On the other hand, the Defendant may choose to resist the discovery. In that case, the Court will be presented with the dilemma of allowing an unlimited fishing expedition or no discovery at all because of the difficulty in fashioning logical and principled limits on what has to be produced. The particularity requirement of Rule 9(b), if enforced, will not only protect defendants against strike suits, but will result in claims with discernable boundaries and manageable discovery limits."

Id.

The purpose of Rule 9(b) is to give Defendant notice of the claims against them. If this court allows Relator to proceed with his current complaint, Defendant will face an overwhelming discovery process with no previous notice of which alleged "fraudulent" acts were committed by the Defendant. Defendant will undoubtedly be asked to provide every Medicare and Medicaid patient record from 2014 to 2017, so Relators may seek whatever evidence is required to prove his conclusory allegations. As a result, Relator will gain an unlimited pass to the discovery process and provide the court no opportunity to fashion parameters on what Relator may request from Defendant.

F. Attorney's Fees

If this honorable court grants this motion, Defendant requests attorney's fees pursuant to 31 U.S.C. § 3730 (c)(4). This statute states as follows:

> "If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment."

Relator's moot allegations lack factual support, specificity, and knowledge, and rise to the level of frivolous pleadings. U.S. ex Rel. Vuyyuru v. Jadhav, 555 F.3d 337, 356 (4th Cir. 2009) (citing Mikes v. Straus, 274 F.3d 687, 705 (2d Cir.2001) (upholding award of attorneys' fees under § 3730(d)(4)'s clearly frivolous element on the basis that plaintiffs allegations clearly had no chance of success, because they were bereft of any objective factual support)).

Defendants also request attorneys' fees and costs pursuant to 28 U.S.C. § 2412.

IV. CONCLUSION

For the foregoing reasons, Defendant respectfully requests this honorable court GRANT Defendant's Motion to Dismiss Plaintiffs-Relators' Complaint.

WHEREFORE Defendants respectfully request:

1. Plaintiff-Relator's Complaint be dismissed in its entirety; and
2. Attorney's fees and costs be awarded to Defendant pursuant to the statutes and authorities cited above; and

3. For such further relief as this Court deems just and proper.

This 19th of June, 2020.

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CERTIFICATE OF SERVICE

The undersigned certifies that the following were served with a copy of the foregoing document on the date and by the method of service identified below:

CM/ECF
All counsel of record
Dated: June 19, 2020

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